Supreme Court, U.S.
FILED
OCT 23 2000
OFFICE OF THE CLERK

No. 98-1768

Supreme Court of the United States

THE BUCKMAN COMPANY,
Petitioner,

v.

PLAINTIFFS' LEGAL COMMITTEE,
Respondent.

On Writ of Certiorari to
the United States Court of Appeals
for the Third Circuit

BRIEF AMICUS CURIAE OF PUBLIC CITIZEN IN SUPPORT OF RESPONDENT

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BRIEF AMICUS CURIAE OF PUBLIC CITIZEN IN SUPPORT OF RESPONDENT

INTEREST OF AMICUS[1]

Public Citizen is a nationwide non-profit advocacy group with more than 150,000 members. It appears before Congress, administrative agencies, and the courts on a wide range of issues, including preservation and enhancement of the state-law civil justice system. Of particular relevance to this case, Public Citizen attorneys have represented plaintiffs and appeared as an amicus curiae in many cases presenting the question whether the Medical Device Amendments to the Food, Drug, and Cosmetic Act ("FDCA") expressly or impliedly preempt state damages claims. For example, Public Citizen attorneys represented the plaintiffs in *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), which figures prominently in the briefs filed in this case. Public Citizen has also represented plaintiffs and amici in cases involving the preemptive effect of other federal regulatory statutes on state-law damages actions. *See, e.g., Freightliner Corp. v. Myrick*, 514 U.S. 280 (1995) (National Motor Vehicle Safety Act); *Hart v. Bayer Corp.*, 199 F.3d 239 (5th Cir. 2000) (Federal Insecticide, Fungicide, and Rodenticide Act); *Roberts v. Florida Power & Light Co.*, 146 F.3d 1305 (11th Cir. 1998) (Atomic Energy Act). Thus, Public Citizen has a longstanding interest in the issue presented in this case.

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[1] Pursuant to Rule 37.6 of this Court, amicus states that no party had any role in writing this brief and that no one other than amicus or its counsel made a monetary contribution to the preparation or submission of this brief. This brief is being filed in accordance with a consent agreement regarding amicus briefs entered into by both parties, which has been filed with the Clerk.

STATEMENT OF CASE AND SUMMARY OF ARGUMENT

Before AcroMed Corporation, which is not a party to this case, could market its pedicle screws, the Medical Device Amendments of 1976 required it to obtain permission from the Food and Drug Administration ("FDA"). A necessary element of its application was a statement of the intended use of the product. AcroMed initially proposed to market the screws for use in the pedicles of the spine. On two occasions, the FDA denied marketing clearance for that use. Thereafter, petitioner Buckman, acting as AcroMed's agent, submitted an application that sought clearance for the pedicle screws' components parts and stated that the intended use of the devices was for fixation of the long bones of the arms and legs. According to the complaint, however, Petitioner knew that AcroMed intended to market the devices exclusively for use in the pedicles. Based upon the misrepresentations of intended use, the FDA granted marketing clearance, the devices were implanted in patients' backs, and patients were injured.

Fairly read, the complaint strongly suggests that AcroMed, as the direct beneficiary of the fraudulent approval, was a full partner in the scheme. JA 13-21. However, because all of the claims against AcroMed have been resolved by a court-approved class action settlement, only the claim against the agent Buckman remains. Since Buckman's role in this matter involved only the fraudulent submission to the FDA, fraud is the only claim asserted against Buckman. In contrast, plaintiffs asserted numerous product liability claims against AcroMed, including the state-law product liability claims typically alleged in such cases. The district court decided that, no matter what proof respondent Plaintiffs' Legal Committee could offer, federal law preempted the claim against Buckman. The court of appeals reversed, and this Court granted review.

Although the question presented encompasses both express and implied preemption, the inapplicability of express preemption to the claim at issue follows directly from *Medtronic*, as the United States demonstrates in its amicus brief. Accordingly, this brief will not address express preemption.

As to implied preemption, the arguments put forth by Petitioner and the United States should be rejected and the court of appeals' decision affirmed. The initial flaw in the implied preemption arguments of Petitioner and the United States is that they seek to avoid the presumption against preemption by recasting this claim as one in an area of traditional federal interest. This case, however, is a damages case alleging a traditional state-law cause of action for fraud. The only unusual wrinkle is the means by which the fraud was perpetrated—misrepresentations to the FDA, whose regulatory clearance was required as a prerequisite to marketing. That wrinkle does not alter the basic preemption analysis because this Court's reasons for the presumption against preemption still apply.

Seeking to identify a conflict between Respondent's claim and a federal interest, both Petitioner and the United States offer only broad statements about the implications of allowing this case to go forward on the merits. These concerns are so general and ill-defined that they would also apply, for example, to claims of design defect, manufacturing defect, or failure to warn, and in cases involving drugs, food additives, and other regulated products. Such broad preemption of state common-law claims is unjustified by any scenario offered by Petitioner or the United States and is flatly at odds with this Court's Supremacy Clause jurisprudence. Moreover, this case does not present a proper vehicle for expanding the Court's

implied preemption doctrine because in the usual product liability claim—brought against the manufacturer, not the manufacturer's agent—fraud-on-the-FDA claims will not have practical significance. This Court should therefore reject Petitioner's invitation to such a significant departure from federalism principles and implied preemption jurisprudence.

ARGUMENT

I. RESPONDENT'S CLAIM DOES NOT INTERFERE WITH ANY FEDERAL INTEREST AND, THUS, IS NOT IMPLIEDLY PREEMPTED.

A. The Presumption Against Preemption Applies In This Case Because The Claim At Issue Implicates Traditional State Concerns.

The Supremacy Clause provides the constitutional authority for the proposition that conflicts between federal and state law are resolved in favor of federal law. *See McCulloch v. Maryland*, 4 Wheat. 316, 427, 4 L. Ed. 579 (1819); *Cipollone v. Liggett Group, Inc.*, 505 U.S. 504, 516 (1992). The Supremacy Clause is restricted by other principles implicit and explicit in the constitutional plan. In particular, the Tenth Amendment provides: "The powers not delegated to the United States by the Constitution, nor prohibited by it to the States, are reserved to the States respectively, or to the people."

In light of the constitutional imperative of federalism, a party seeking preemption of state law bears a heavy burden. There is a strong presumption *against* preemption that may be overcome only by "clear and manifest" congressional intent to the contrary. *Hillsborough County, Florida v. Automated Medical Laboratories, Inc.*, 471 U.S. 707, 715 (1985); *see also Hawaiian Airlines, Inc. v. Norris*, 512 U.S. 246, 252 (1994);

Wisconsin Public Intervenor v. Mortier, 501 U.S. 597, 605, 611 (1991).

Thus, "[c]onsideration under the Supremacy Clause starts with the basic assumption that Congress did not intend to displace state law." *Maryland v. Louisiana*, 451 U.S. 725, 746 (1981). Put differently, "[p]reemption of state law by federal . . . regulation is not favored 'in the absence of persuasive reasons—either that the nature of the regulated subject matter permits no other conclusion, or that Congress has unmistakably so ordained.'" *Chicago and North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311, 317 (1981) (quoting *Florida Lime & Avocado Growers, Inc. v. Paul*, 373 U.S. 132, 142 (1963)). The presumption against preemption is even stronger where "Congress [has] legislated . . . in a field which the States have traditionally occupied, [involving] the historic police powers of the States." *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947). In other words, the presumption is "that state and local regulation of health and safety matters can constitutionally coexist with federal regulation [because] the regulation of health and safety matters is primarily and historically a matter of local concern." *Hillsborough County*, 471 U.S. at 716, 719. This presumption applies when a defendant is seeking preemption of state tort remedies because, in that situation, preemption would displace the historic power of the states to protect the health and safety of their citizens. *See, e.g., Medtronic*, 518 U.S. at 484-86.

Moreover, as in this case, where the allegedly preemptive federal regulatory scheme does not itself provide a damages remedy and preemption would leave injured individuals without any state *or* federal remedy against the tortfeasor, this Court has ascribed preemptive intent to Congress only in the most compelling circumstances. *See*

English v. General Electric Co., 496 U.S. 72, 87-90 (1990); *Silkwood v. Kerr-McGee Corp.*, 464 U.S. 238, 251 (1984).

Both Petitioner and the United States acknowledge these principles. They argue, however, that the presumption against preemption does not apply here because the fraud claim at issue intrudes on an area of federal, not state, concern. This reasoning is flawed, primarily because Petitioner's claim *does* arise out areas of traditional state concern. The claim is based on state common-law fraud principles and seeks common-law damages for injuries suffered by individuals that would not have occurred but for the allegedly fraudulent conduct. The contrary view of Petitioner and the United States is based on the artifice that the truthful reporting obligations imposed by the FDCA are intended to serve only government interests, not the interests of the citizens who use the products approved for marketing by the FDA.

The statute and regulations pursuant to which the FDA acts, however, including the requirement of truthful submissions, are intended to protect patients who use drugs and medical devices, not to protect a government interest in truthful reporting as an end in itself. The state's interest, as implicated by Respondent's claim, is to compensate injured patients. In other words, both the state damages action and the federal truthfulness requirements are intended to protect patients' health and safety. *See Medtronic*, 518 U.S. at 485 (recognizing historic state interest in matters of health and safety). Therefore, the state-law claim and the federal regulations are complementary, not conflicting.

Arguing that the presumption against preemption does not apply in cases that implicate "an area of paramount federal concern," US Br. 19, Petitioner and the United States rely on *Boyle v. United Technologies Corp.*, 487 U.S. 500 (1988). Pet.

Br. 31; US Br. 19. There, the plaintiff had brought a damages action for injuries caused by a product that the defendant had manufactured pursuant to specifications dictated by a contract with the United States. The Court held that design defect suits, although an area of traditional state concern, implicate "unique" federal interests where the claims involve "obligations to and rights of the United States under its contracts" and "civil liabilities arising out of the performance of federal procurement contracts." *Boyle*, 487 U.S. at 504-06. The outcome of such a lawsuit, the Court held, even one between private parties, would directly affect the government's interests, either the contractor's willingness to manufacture the design specified or the price charged. *Id.* at 507.

In contrast, this case presents no such "unique" federal interests. Not even the United States suggests that the outcome of the lawsuit would affect the government interest it identifies—the FDA's ability to obtain accurate information from regulated entities. US Br. 18. *Cf. Pacific Gas & Energy v. Energy Resources Comm'n*, 461 U.S. 190 (1983) (no preemption of state regulation of economic aspects of atomic power plants where federal government occupied field of atomic safety but not economic effects of atomic power plants).

Instead, *Miree v. DeKalb County*, 433 U.S. 25 (1977), is the analogous case here. There, the plaintiffs sued the County for, among other things, breach of contract for maintaining a dump adjacent to an airport in violation of a contract between the County and the United States. The plaintiffs alleged that they were third-party beneficiaries to the contract, that the dump attracted birds that had caused an airplane crash, and that plaintiffs were entitled to damages for injuries suffered in the crash. The court of appeals had held that federal common law was applicable to the breach of contract claim. It had reasoned that the fact that the United

States was a party to the contract at issue, which was entered into pursuant to a federal statute, "necessit[ated] uniformity of decision." This Court reversed, citing the fact that the resolution of the claim would have no direct effect on the United States or its Treasury. The instant case is no different. Federal involvement in the factual background of the case does not support the conclusion that federal interests are at stake in this state-law damages claim.

B. Allowing The Claim To Proceed Will Not Harm Any Legitimate Federal Interest.

Whether or not the presumption against preemption of state law applies, the claim is not preempted because it does not conflict with any federal interest. The implied preemption arguments of Petitioner and its amici stray far from the facts of this case and are inconsistent with the preemption principles established by the Constitution and this Court. Moreover, their theories for a finding of implied preemption are so broad as to apply to a significant portion of product liability law—to design defect claims, manufacturing claims, and fraud claims, for example—even in situations where the agency subsequently discovered fraud and took action against the wrongdoer.

The United States points to three federal interests in support of implied preemption of Respondent's fraud-on-the FDA claim, and its arguments encompass those of Petitioner. Although the United States indicates throughout its brief that it intends to address only fraud-on-the FDA claims, its suggested bases for conflict preemption could be applied broadly to many sorts of product liability claims. As discussed below, however, none of the Government's three points justifies a finding of preemption here.

1. Attempting to fashion a conflict between Respondent's state-law claim and the FDA's interests, the United States identifies a federal interest in "regulating information that a regulated entity must submit to the FDA." US Br. 23. By its very nature, however, a claim premised on allegations that the FDA's own regulations were violated is consistent with the FDA regulations setting forth the nature of required submissions.

The argument in favor of preemption fares no better when characterized as a conflict with the "interest in permitting FDA to decide for itself whether it has been defrauded and, if so, what remedy to seek." US Br. 21. In this regard, Petitioner reminds the Court that the FDCA does not establish a private right of action. Pet. Br. 36. However, the claim at issue is not brought under the FDCA. It is not a claim to enforce the FDCA. It is a claim under state-law principles and seeks damages for injuries suffered, not by the FDA, but by individual patients. Like a negligence per se claim or the manufacturing and labeling claims at issue in *Medtronic*, state law may recognize a cause of action for violation of state-law duties embodied in a federal statute, even where the federal statute does not create a private federal right of action. *See Medtronic*, 518 U.S. at 495 ("Nothing in [express preemption provision] denies Florida the right to provide a traditional damages remedy for violations of common-law duties when those duties parallel federal requirements.") (majority decision); *id.* at 513 ("To be sure, the threat of a damages remedy will give manufacturers an additional cause to comply [with federal regulations], but the requirements imposed on them under state and federal law do not differ.") (O'Connor, J., concurring in part and dissenting in part).

Although the United States asserts that allowing Respondent to pursue this state-law claim for damages would

interfere with the FDA's enforcement authority, litigation of the claim would not in fact preclude the FDA from taking any enforcement action in regard to the conduct at issue. Nonetheless, the Government offers three theories to support this purported conflict. None of the three, however, fits within established principles of conflict preemption. Moreover, the breadth of the Government's arguments would nullify *Medtronic* and the Government's own position, expressed in *Medtronic*, in *Smith Industries Medical Systems v. Kernats*, *see* Brief for United States as Amicus Curiae in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405 (filed Dec. 1997), and in this case, US Br. 11-12, that the MDA does not expressly preempt the vast majority of damages claims.

First, the United States says the conflict manifests itself in the possibility that juries in different states might reach judgments that differ from the FDA's with respect to whether Petitioner committed fraud. In this case, that possibility is far-fetched because the facts make plain that the FDA does not intend to make any judgment as to Petitioner's alleged fraud. In any event, even if possible, that scenario does not trigger conflict preemption. Indeed, the United States never explains in what way differing state-law verdicts on the question of whether Petitioner's misrepresentations to the FDA caused injury to plaintiffs would present an actual conflict with or impediment to the FDA's ability to enforce its regulations.

Moreover, the possibility that different juries will reach different conclusions based on the same facts is in no way unique to "fraud-on-agency" claims. For example, the possibility of different adjudications on similar facts existed throughout the pedicle screw litigation, as it does in any series of cases arising from toxic torts or product liability claims. That fact alone has no logical connection to the question of implied preemption. *See Silkwood*, 464 U.S. at 256 (accepting

"tension" between conclusion that safety regulation is exclusive federal concern and conclusion that states may award damages based on their own laws of liability).

Because it is not tied to the claim at issue in this case, the United States' argument would swallow much of product liability litigation in cases where the product at issue received federal marketing clearance. For example, the United States itself recognizes that premarket approval of medical devices does not preempt state-law design defect claims, negligent manufacturing claims, or failure-to-warn claims. *See generally* Brief for United States as Amicus Curiae in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405 at 14-18. Yet the Government's argument would be equally applicable to such state-law tort claims since those claims also implicate federal regulations as to which the FDA has at least primary enforcement authority. Accordingly, if this Court were to create a new super-category of "conflict" preemption for state-law damages actions based on the possibility that some of those cases would result in decisions different from the one a federal agency might have made (whether or not the agency had made any decision at all), plaintiffs would lose their sole means of obtaining a remedy for injuries caused by new medical devices, drugs, food additives, and other products subject to premarket federal scrutiny.

Second, the United States argues that the FDCA does not envision damages remedies for injured patients and that, therefore, to allow such remedies would "distort" the statute's penalty scheme. US Br. 23. This argument also is stated so broadly as to threaten a significant portion of product liability and personal injury damages claims, including claims that the FDA itself states do not warrant preemption. The FDCA's remedial scheme is directed at punishing wrongdoers and righting regulatory wrongs. *See* US Br. 22 (listing potential

penalties). True, the FDCA does not include a private damages remedy. However, the "FDA's authority to require manufacturers to recall, replace, or refund defective devices is of little use to injured plaintiffs, since there is no indication that the right is available to private parties, the remedy would not extend to recovery for compensatory damages, and the authority is rarely invoked, if at all." *Medtronic*, 518 U.S. at 487 & n.7 (opinion of Stevens, J.). Similarly, although the FDA may impose civil money penalties, 21 U.S.C. § 333(g)(1)(A), that money goes to the federal government, not to injured patients. Thus, far from offering a reason *for* preemption, the Government's point supports a finding *against* preemption. *See also Medtronic,* 518 U.S. at 513 ("Section 360k does not preclude States from imposing different or additional *remedies*, but only different or additional *requirements*.") (O'Connor, J. concurring); *Silkwood*, 464 U.S. at 251 ("Congress would [not], without comment, remove all means of judicial recourse for those injured by illegal conduct.").

In fact, the United States' position on express preemption is consistent with the view that damages actions are not impliedly preempted. Certainly, the Government's amicus briefs in *Medtronic* and *Smith Industries Medical Systems v. Kernats* in no way suggested that the FDA felt threatened by the damages claims at issue in those cases. *See* Brief for United States as Amicus Curiae in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405 (filed Dec. 1997); Brief for United States as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035 (filed Mar. 15, 1996). To the contrary, the United States' brief in *Kernats* argued (at 14-18) that the premarket approval process for medical devices does *not* preempt product liability claims. Yet the United States' argument here, although offered with regard to only a single damages claim, simply has no logical stopping point. To hold

that Respondent's claim is preempted because a damages remedy is not available under the FDCA thus threatens "effectively [to] preclude[] state courts from affording state consumers any protection from injuries resulting from a defective medical device." *Medtronic*, 518 U.S. at 487.

Third, the Government asserts that Respondent's state-law claim would interfere with the FDA's discretion to decide which, if any, statutory remedy to pursue. Again, the Government fails to tie this argument to the claim at issue. The same argument could be made for all sorts of state-law damages actions involving injuries caused by regulated products. Moreover, the Government misunderstands the nature of a state-law damages action such as the fraud claim here by suggesting that the action seeks to remedy an offense against the FDA. Such claims do not seek to vindicate an institutional government interest in truthful submissions; they seek remedies for injuries suffered by consumers. Although Petitioner made the alleged misrepresentations here to the FDA, the FDA was not harmed. Patients were harmed. Although labeled a claim for "fraud on the FDA," the victim of the fraud was not the FDA. The victims were the patients who used the device, thereby relying on the misrepresentations to their detriment. JA 21 (¶133). That is, by lying to the FDA, Petitioner effectively lied to the patients who subsequently used the product.

The story of the Bjork-Shiley conveco-concave heart valve ("C/C valve") illustrates that allowing claims such as Respondent's to go forward does not threaten to interfere with the FDA's interests. In 1979, the FDA granted to Shiley, Inc. premarket approval for the C/C valve. *Michael v. Shiley, Inc.*, 46 F.3d 1316, 1320 (3d Cir.), *cert. denied*, 516 U.S. 815 (1995). Throughout the next 6½ years, the FDA grew increasingly concerned about the valve's numerous reported fractures. At

the same time, Shiley repeatedly attempted to thwart FDA efforts to regulate and monitor the C/C valve by delaying required reporting, failing to notify the FDA prior to implementing new tests, failing to submit PMA supplements in a timely manner, and implementing changes prior to substantiation by sufficient testing. *See* FDA Management and Enforcement, Hearing Before the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce, House of Representatives, 1st Sess. 2 (Sept. 12, 1991). Eventually, Shiley withdrew the valves from the market and, on November 24, 1986, ceased all production of C/C valves. *Michael v. Shiley*, 46 F.3d at 1321. Although the FDA had the authority to require the manufacturer to repair or replace the device or to take other actions, *see* 21 U.S.C. § 360h(b), it did not invoke that authority. For the thousands of Americans implanted with the valve, several hundred of whom had died when the valves broke, *see Bowling v. Pfizer*, 143 F.R.D. 141, 147 (S.D. Ohio 1992), state law afforded the only remedy.

Under Petitioner's and the Government's new formulation of conflict preemption, because the juries in the numerous C/C valve product liability cases might reach different verdicts as to whether the valve had a design defect, whether Shiley had inadequately warned patients of the risks of the valve, and whether Shiley's conduct warranted punitive damages, all of the patients' lawsuits against Shiley should have been impliedly preempted. Under this theory, because the FDA had approved Shiley's premarket approval application, because the FDCA authorized the agency to seek remedies that did not include compensatory damages, *and/or* because the FDCA gave the choice of regulatory remedies to the FDA alone, none of the claims for compensation for deaths caused by the C/C valve could have gone forward. Moreover, their theory would support preemption even in cases where the agency had made express findings of wrongdoing or withdrawn marketing

approval. Tellingly, although in several cases Shiley argued for express preemption, *see, e.g.*, *Michael v. Shiley*, 46 F.3d 1316, the FDA did not file an amicus brief in a single one of the C/C valve cases to suggest that allowing the state-law claims to go forward would interfere with the agency's interests. The United States did, however, file amicus briefs arguing against express preemption in several cases involving medical devices. *See, e.g.*, Brief for United States as Amicus Curiae in *Smith Industries Medical Systems v. Kernats*, S. Ct. No. 96-1405; Brief for United States as Amicus Curiae in *Medtronic v. Lohr*, S. Ct. No. 95-754, 1996 WL 118035; Brief for the Food and Drug Administration as Amicus Curiae in *Duvall v. Bristol-Myers Squibb Co.*, No. 94-1520 (4th Cir.) (dated Mar. 1995); Brief for United States as Amicus Curiae in *Talbott v. Bard*, No. 94-1951 (1st Cir.) (dated Nov. 1994).

Thus, as this Court stated with regard to the scope of express preemption of medical device claims, the Government's justifications for conflict preemption in the circumstances presented here would "have the perverse effect of granting complete immunity to an entire industry that, in the judgment of Congress, needed more stringent regulation" to protect patients. *Medtronic*, 518 U.S. at 487 (opinion of Stevens, J.). Notwithstanding that the Government's intention is narrow, its rationale, broadly applied, risks immunizing not just the medical device industry but manufacturers of drugs and other regulated products as well.

2. Petitioner and the United States also characterize the purported conflict as one with the FDA's market clearance decision. Petitioner, for example, suggests that Respondent's fraud claim infringes on the FDA's authority "to decide whether a device is substantially equivalent to a pre-1976 device and to respond to fraud or misrepresentation in the clearance process." Pet Br. 36. The claim, however, does not challenge the FDA's

decision that AcroMed's screws were substantially equivalent to a pre-1976 device marketed for use in the long bones. The factual issue is whether the intended use stated in the marketing application submitted to the FDA—for fixation of long bones—was the true intended use. Thus, the question of whether Petitioner made misrepresentations does not depend on examination of the FDA's decisionmaking. Furthermore, Respondent's complaint alleges that, just prior to submission of the "fraudulent" marketing application, the FDA had rejected applications for clearance of the true intended use—for fixation of the pedicles of the spine. JA 13-14. Indeed, as Petitioner points out, Pet. Br. 9, when the FDA finally cleared the component parts of the screws for use in the long bones, it required AcroMed "to warn that it had 'NOT BEEN APPROVED FOR PEDICULAR APPLICATION.'" *Id.* (citing JA 19); *see also* JA 124 (1991 letter from FDA to AcroMed stating that promotion of screws for use in pedicles violates FDCA because such use requires premarket approval). Accordingly, the question of whether the application would have been approved had Petitioner not misrepresented the intended use is not a matter of second-guessing the FDA since the FDA itself answered that question in the affirmative more than once.

Petitioner argues that, although the FDA rejected premarket clearance applications for spinal use of the screws in the mid-1980s, to allow patients a remedy for the fraud today would be inconsistent with the FDA's decision in 1998 (and in 1995 with respect to one particular screw intended for one particular use), to allow the devices to be marketed for use in the spine. Pet. Br. 39; *see* 63 Fed. Reg. 40025, 40032 (1998). However, the subsequent marketing clearance came a decade after the alleged fraud. The FDA's decision in 1998 to grant marketing clearance for use in the spine as treatment for certain conditions was not (and, contrary to Petitioner's suggestion, did

not purport to be) a determination whether Petitioner's 1985 application misrepresented the product's intended use. *See* US Br. on Cert. 14. Petitioner is correct that the FDA's 1998 rulemaking concluded that the screws should remain on the market. That fact may be relevant on the issues of causation and damages. For example, Petitioner could argue to a jury that the 1998 clearance granted to some pedicle screw systems to treat specific conditions demonstrates that those devices were worthy of being marketed for those conditions in 1986, notwithstanding Petitioner's misrepresentations, and that the misrepresentations therefore did not harm patients. However, Respondent's complaint does not address whether the screws should be on the market today; the only remedy sought is damages. The claim is therefore not inconsistent with the FDA's 1998 action.

For this and other reasons, *Chicago & North Western Transportation Co. v. Kalo Brick & Tile Co.*, 450 U.S. 311 (1981), is not on point here. In *Kalo Brick*, the petitioner had sought and obtained permission from the Interstate Commerce Commission ("ICC") to stop rail service on a certain line. When the service stopped, the respondent sued the petitioner for damages resulting from the cessation of service. This Court held that the lawsuit was preempted because it required the state court to evaluate the reasonableness of closing the line, an evaluation Congress had assigned to the ICC. The Court pointed out that the Interstate Commerce Act offered administrative remedies but that the respondent had not availed itself of those remedies. Although the Act did not offer a private damages remedy, the available administrative remedies would have allowed the respondent to object to and seek reversal of the agency decision allowing cessation of service.

In contrast, here, Respondent had no administrative remedies to pursue. The only administrative avenue available

—petitioning the FDA to remove AcroMed's screws from the market—would not help already-injured patients. Furthermore, unlike the situation in *Kalo Brick*, when the FDA cleared the screws for marketing in 1986, many patients who later received the pedicle screws would not even have known that they would some day need back surgery. In addition, the claim in *Kalo Brick* did not involve fraud. Here, the nature of the claim is such that Respondent's clients did not know of the problem and suffered no injury until after the FDA granted marketing clearance, AcroMed began promoting its screws solely for an unapproved use, and the individuals represented by Respondent were implanted with and harmed by the pedicle screws. Moreover, *Kalo Brick* left open the question whether a state-law claim would be preempted if the agency were empowered to rule on an issue but had not done so. *Id.* at 327 ("But we need not decide whether a state-court suit is barred when the Commission is empowered to rule on the underlying issues, because here the Commission has actually addressed the matters respondent wishes to raise in state court."). Here, of course, the FDA has not ruled whether its 1986 decision would have been different had Petitioner not misrepresented the devices' intended use, nor does it seem at all likely ever to do so. *See* US Br. on Cert. 14. Finally, as discussed above, the FDA's prior rejection of two applications for the devices at issue when offered for use in the pedicles suggests that a damages action is consistent with the agency's 1986 view. *See supra* p. 16.

The United States also relies heavily on *Arkansas Louisiana Gas Co. v. Hall*, 453 U.S. 571 (1981). That case is inapposite. An award of damages in that case would have effectively afforded the plaintiff a retroactive change in a filed rate for natural gas. However, the Natural Gas Act authorized only the Federal Power Commission to change rates and prohibited even the Commission from doing so retroactively.

On this basis, the damages suit was held to conflict with the Act. In contrast, the FDCA does not concern economic regulation of the drug and medical device industries. Whereas in *Arkla* the remedy sought would have had an effect forbidden under the federal statute (retroactive change in rates), here the remedy sought (damages for personal injury) would have no effect on the matters regulated under the FDCA.

3. Petitioner and the United States also contend that Respondent's claim is preempted because to litigate such claims might involve the FDA in litigation discovery. *See* Pet. Br. 44; U.S. Br. 28. Under this Court's preemption jurisprudence, however, the possibility that private parties would seek discovery from the FDA or FDA officials is not a ground for finding preemption of tort claims. Although both Petitioner's and the Government's briefs attempt to tie this argument to undesirable "practical consequences," neither make any effort to tie the argument to preemption principles or case law. The question whether some other principle of law is implicated by attempts to depose agency officials is not presented here. *See, e.g., United States ex rel. Touhy v. Ragen*, 340 U.S. 462 (1951).

Moreover, the facts of this case belie Petitioner's and the Government's discovery argument. In the MDL court, Respondent did seek discovery from the FDA. However, since the district court dismissed the fraud-on-the-FDA claims against Petitioner and other defendants on preemption grounds early in the litigation, none of that discovery can reasonably be attributed to the claim at issue here. Petitioner's list of discovery allowed by the Court, Pet. Br. 44-45, is thus misleading in that it suggests that the discovery was taken in connection within the fraud-on-the-FDA claim asserted against it. In fact, to our understanding, much of the discovery was sought in response to *defendant* AcroMed's attempt to use the FDA's marketing clearance as a state-law defense. These facts

underscore the breadth of the implied preemption argument urged by Petitioner and its amici here since the discovery related to other types of product liability claims and to other defendants. These facts further show that if the discovery argument supports a finding of implied preemption here, it likewise supports implied preemption of many sorts of traditional state-law product liability claims.

II. THE IDIOSYNCRATIC NATURE OF RESPONDENT'S FRAUD-ON-THE-FDA CLAIM UNDERSCORES THE NARROWNESS OF THE QUESTION PRESENTED.

Although some of the arguments made by Petitioner and the United States are very broad, this case in fact presents a very narrow legal question. This Court's resolution of the preemption issue should affect very few, if any, future cases.

The fraud-on-the-FDA theory is before this Court only because of the presence of an unusual defendant, Buckman, who acted as an agent for the principal defendant, AcroMed. As AcroMed's consultant, Buckman did not have any contact with bone screw patients or their doctors. Therefore, ordinary tort claims for design and manufacturing defects, failure to warn, and common-law fraud against the product manufacturer—such as those brought against AcroMed and later resolved in a class action settlement, *see In re Orthopedic Bone Screw Product Liability Litigation*, 176 F.R.D. 158 (E.D. Pa. 1997)—could not be brought against Petitioner. The *only* theory of liability against Petitioner necessarily centers around Petitioner's interactions with AcroMed and the FDA.

In an ordinary product liability case, however, even if a fraud-on-the-FDA claim were asserted against a drug and device manufacturer, the lawsuit would not center on that

claim. In such a case, the fraud-on-the-FDA claim has no practical importance because the measure of damages relating to the plaintiff's injuries from the device is the same under ordinary tort claims, which are therefore sufficient in themselves to make the plaintiff whole. In addition, the fraud-on-the-FDA claim may well be more difficult to prove than typical tort claims because it may involve agency information that is difficult to obtain. *See United States ex rel. Touhy,* 340 U.S. 462. Thus, as a practical matter, a fraud-on-the-FDA theory will only have potential relevance in the highly unusual context presented here, where the defendant is a manufacturer's agent who deals only with the manufacturer and the FDA, not with doctors and patients.

The practical insignificance of this case is demonstrated by the briefs filed by Petitioner, which, rather than focusing on the case as properly framed, beseech this Court to resolve issues that are not presented by the ruling below or by the facts of this case. Thus, Petitioner has urged this Court to address issues not in the case, Pet. for Cert. at I (two questions presented, which this Court narrowed and re-drafted as one), to overrule *Medtronic* on matters unrelated to the question presented, Pet. Br. 45-50, and to extend its ruling to agencies other than the FDA, *id.* at 39-40, which have very different regulatory structures under vastly different governing statutes. What Petitioner does not do, presumably because it cannot, is point to a single case in which a medical device or drug manufacturer has been held liable by a judge or jury on a fraud-on-the-FDA theory, such as that asserted against Buckman. Thus, Petitioner has completely failed to support its assertion that this claim threatens to "Interfere Substantially With Federal Government Operations." *Id.* at 40.

Indeed, even as to a "consultant" defendant such as Petitioner, the practical effect of the fraud-on-the-FDA theory

would be minimal, if not non-existent. Fraud-on-the-FDA claims against agents inevitably will spur claims for indemnity against the principal tortfeasor/manufacturer, on the ground that it was the manufacturer that harmed the plaintiffs by marketing a device that was defective or not accompanied by appropriate warnings. In the end, fraud-on-the-FDA claims against consultants such as Buckman will fall back on ordinary common-law theories of liability against principals such as AcroMed, which underscores the extremely narrow nature of the question presented.

One additional factor counsels against a broad preemption ruling here. The contours of the state cause of action for "fraud-on-the-FDA" are sufficiently unclear as to give this Court pause about exactly what Petitioner is asking it to find preempted. To be sure, the complaint sets forth various facts that Respondent claims should give rise to liability on a fraud-on-the-FDA theory. JA 13-21. However, the only arguably relevant general statement of law involving the significance of deceptive submissions to a regulatory agency does not recognize a fraud-on-the-agency cause of action, either generally or as against a non-manufacturer agent such as Respondent. *See Restatement (Third) of Torts: Products Liability* § 4, comment e (Amer. Law Inst. 1998). Rather, the Restatement makes the unremarkable point that when a manufacturer defendant provides false or misleading information to a regulatory agency in an ordinary design-defect or failure-to-warn case, the manufacturer's reliance on the state-law defense of regulatory compliance "is entitled to little or no weight." *Id.*

In sum, a ruling from this Court on the case actually before it, rather than the case Petitioner wishes were here, will affect few if any product liability cases. That fact may be a reason to dismiss the writ of certiorari as improvidently

granted. At the very least, it is reason to approach this case very narrowly and rule only on the precise issue before the Court, leaving broader preemption issues for another day.

CONCLUSION

For the foregoing reasons, the judgment of the court of appeals should be affirmed.

Respectfully submitted,

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October 23, 2000